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New surgical instrumentation reduces the revision rate of Unicompartmental Knee Replacement: A propensity score matched comparison of 15,906 knees from the National Joint Registry

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ABSTRACT

Background: Unicompartmental knee replacement (UKR) offers advantages over total knee replacement but has higher revision rates. New instrumentation known as Microplasty was introduced to address this. The aim was to compare the revision rates of UKRs implanted with Microplasty and traditional instrumentation (Non-Microplasty).

Methods: National Joint Registry (NJR) data was used to propensity score match 15,906 UKRs (7,953 Microplasty and 7,953 Non-Microplasty) for important patient, implant and surgical factors. Implant survival rates were determined using the Kaplan-Meier method and compared using Cox regression models in a multilevel model.

Results: The 5 year implant survival for Microplasty and Non-Microplasty UKRs were 96.7% (95% CI 96.0%-97.2%) and 94.5% (CI 93.8-95.1%) respectively. The revision rate for Microplasty UKR was significantly lower than that of Non-Microplasty UKRs (Hazard ratio (HR)=0.77, p=0.008). Compared with Non-Microplasty UKRs, the revision rate of Microplasty UKRs implanted during the year after introduction of Microplasty was lower but the difference was not significant (HR 0.86, CI 0.67-1.10, p=0.23), whereas for those implanted more than a year after introduction the difference was significant (HR 0.69, CI 0.54-0.89, p=0.004).

Conclusion: The use of Microplasty instrumentation has resulted in an improved 5 year UKR survival. Microplasty UKR implanted during the first year after introduction had a small, non-significant decrease in revision rate. As the revision rate did not increase this suggests that there is no adverse learning curve effect. Microplasty UKRs implanted after this transition period had a revision rate 31% lower than the Non-Microplasty group.

Level of evidence: II

Key words: Microplasty, Non Microplasty, Unicompartmental Knee Arthroplasty

Abstract word count: 245 words

1. INTRODUCTION

Total and Unicompartmental knee replacement (TKR, UKR) are the two main treatments for knee osteoarthritis which has failed to respond to conservative therapy, with evidence that UKR is appropriate in up to 50% of cases [1]. Although UKR is more cost effective [2] and results in better functional outcomes [3], revision rates remain significantly higher in joint registries [4-6]. This is not the case in specialist centres with high volume surgeons who achieve similar revision rates to TKR [7-9].

The high revision rate of UKR may, in part, be a result of poor positioning of the implant or other technical problems with the operation, which is made particularly difficult with minimally invasive approaches where intra-operative visualisation is restricted [10, 11]. This is relevant given the most commonly used UKR is the Phase 3 Oxford UKR [4], which is implanted using a minimally invasive approach. Phase 3 instrumentation, which was introduced over 20 years ago, is difficult to use: For example the operating surgeon has to judge by eye the height of the tibial cut and the orientation of the femoral component, making inexperienced surgeons susceptible to errors.

New instrumentation known as Microplasty was introduced to make the operation simpler, more reproducible and more reliable. The use of Microplasty instrumentation has been steadily increasing. The instrumentation includes a stylus system for selecting tibial resection level, a femoral drill guide linked to an intramedullary rod to help femoral component positioning, slotted saw guides and instruments to protect the medial collateral ligament and avoid impingement [12] (Figure 1). Although the Microplasty instrumentation has been shown to improve implant positioning [13-16] it is currently unknown whether it makes any difference to the revision rate. Additionally, as Microplasty instrumentation is more complex than the Phase 3 instrumentation (Non-Microplasty), there is a concern that the outcome might be worse when it is first used due to learning curve issues.

The National Joint Registry for England, Wales, Northern Ireland and Isle of Man (NJR) is the world's largest arthroplasty register [4]. NJR data was utilised to compare the revision rates following Microplasty and Non-Microplasty Oxford UKRs. The null hypothesis was that there would be no difference in UKR implant survival between groups. To ensure that any difference in implant performance was due to the instrumentation rather than other

factors, Microplasty and Non-Microplasty cases were matched on patient, surgeon (including caseload) and implant factors.

2. MATERIALS AND METHODS

A retrospective observational study was performed using NJR data [4]. The NJR database includes information on patient factors (including age, sex, body mass index), implant factors (including component design and size) and surgical factors (surgical indication, operating surgeon grade) for each procedure. The database is linked to mortality data from the Office of National Statistics.

The dates at which Microplasty Instrumentation was introduced to each UK hospital (changeover date) were obtained and supplied to the NJR. Prior to this date, or if there was no date, the hospital was assumed to be using the Non-Microplasty instrumentation. After this date it was assumed they were using Microplasty Instrumentation. During the first year after the changeover date it was assumed that there was a transition period which included the surgeon's learning curve and the changeover between systems. In Oxford, prototype Microplasty instruments have been used for many years and there was no exact date of their changeover to Microplasty, so all UKRs conducted in Oxford were excluded from this study.

Anonymised patient data were extracted from the NJR database which included all primary Oxford UKRs implanted between 1st January 2012 to 31st December 2017 (n=28,273), given Microplasty was first used outside Oxford in 2012. The NJR linked the changeover date to Microplasty to the patient data. After data cleaning there were 23,234 medial UKRs (11,024 Microplasty and 12,210 Non Microplasty UKRs) eligible for study inclusion (Figure 2).

Given the potential for patient, implant and surgical factors [17-31] other than instrumentation to affect the revision rate, *a priori* matching for these factors between groups was conducted using propensity scores (Table 1 for full list). Surgical factors included surgeon caseload, which was defined as the average number of UKRs done per year and stratified into low (<10 cases/yr), medium (10 to <30 cases/yr) and high volume (≥ 30 cases/yr) as described previously [26].

A multilevel logistic regression model was used to generate a propensity score representing the probability that a patient received a Microplasty assisted UKR. This approach controlled for clustering at the hospital level. The specific variables patients were matched on were; age, gender, primary diagnosis, unilateral/bilateral UKRs, ASA grade, chemical

thromboprophylaxis, mechanical thrombopropylaxis, operating surgeon grade, surgeon caseload, surgical approach, operating technique and implant fixation (Table 1). Body mass index (BMI) was not used for matching given it had a large proportion of missing data, but was similar between groups both before and after matching.

One to one matching on the logit of the propensity score with a 0.02-SD calliper width was utilised. Greedy matching without replacement was used given its superior performance for estimating treatment effects [32]. Standardized mean differences (SMDs) were examined both before and after matching to assess for any covariate imbalance between the Microplasty and Non Microplasty UKRs, with SMDs of 10% or more considered suggestive of covariate imbalance [32]. After matching, 15,906 UKRs (7,953 Microplasty and 7,953 Non Microplasty UKRs) were included for analysis (Figure 2). Microplasty UKRs were divided into procedures conducted within the first year after Microplasty's introduction and after the first year to explore the learning curve effect.

2.1 Statistical analysis

Outcomes of interest were: (1) implant survival and revision rates (2) indications for revision surgery.

Cumulative implant survival was determined using the Kaplan-Meier method. The endpoint for implant survival was revision surgery (any component removed, exchanged or added). Cumulative implant revision rates were compared between groups, using Cox regression models. To account for clustering within the matched cohort a robust variance estimator was used in regression models. Univariable and adjusted models were also assessed. The adjusted models included covariates with residual imbalance after matching (SMD of 10% or more) [32].

A secondary analysis was undertaken based on the revision rate per 100 component years. This was calculated for both groups by dividing the number of revisions by the total number of observed component years (mean follow up multiplied by number of knees) as per the Australian Joint Registry [5]. 95% CI were calculated using the Clopper Pearson exact method. Revision rates between groups were compared using the chi squared proportional test.

To compare the indications for revision surgery the revision rates per 100 component years for each revision indication were calculated. The proportional Chi-squared test with Yate's correction was used to test for differences between Microplasty and Non-Microplasty except when the observed frequencies were below 5 in which case the Fisher Exact Test was utilised.

All statistical analyses were performed using Stata (Version 15.1; Lakeway Drive TX) except propensity score matching which was performed using R (Version 3.4.0; R Foundation for Statistical Computing, Vienna, Austria). P-values of <0.05 were considered significant, with 95% confidence intervals (CI) presented.

2.2 Ethics approval and consent to participate

The study was approved by the NJR Research Sub-Committee (RSC2017/17). As patients provide informed consent for inclusion of their data in the NJR for purposes including research, institutional review board approval was not required.

3. RESULTS

The matched cohort included 15,906 UKRs with 7,953 Microplasty UKRs and 7,953 Non-Microplasty UKRs. The mean age at surgery was 64.5 years (SD 9.5), with 7,235 females (45.5%) and 8,671 males (54.5%). The mean BMI was 30.4 kg/m^2 (SD 5.0) with the primary indication for surgery being osteoarthritis in 15,752 knees (99.0%).

Patient, surgical (including caseload) and implant characteristics were well balanced between the Microplasty and Non Microplasty groups after propensity score matching (Table 1). The only covariates with some residual imbalance were surgeon grade and surgeon caseload, which, when adjusted for in the regression models, did not change the findings.

In the matched cohort, the mean follow up for Microplasty and Non Microplasty UKRs were 2.3 years (SD 1.3) and 3.3 years (SD 1.8) respectively. In total 451 knees underwent revision surgery. There were 160 (2.0%) revisions in the Microplasty group and 291 (3.7%) revisions in the Non Microplasty UKR group.

The 5-year cumulative implant survival rates were 96.7% (95% CI 96.0%-97.2%) for Microplasty and 94.5% (95% CI 93.8-95.1%) for Non-Microplasty UKRs (Figure 3). Microplasty UKRs had a significantly reduced revision rate compared with Non-Microplasty UKRs (HR=0.77, CI 0.64-0.94; p=0.008).

Subgroup analysis of Microplasty UKR inserted within a year of its introduction (n=2,424) and those inserted more than a year after its introduction (n=5,529) had 4 year implant survival rates of 96.2% (CI 95.3-97.0) and 96.8% (CI 95.6-97.8) respectively (Figure 4). Microplasty UKRs inserted within one year of its introduction had non-significantly reduced revision rates when compared to Non-Microplasty UKRs (HR 0.86, CI 0.67-1.10, p=0.23). Microplasty UKRs inserted more than a year after its introduction had significantly reduced revision rates compared to Non-Microplasty (HR 0.69, CI 0.54-0.89, p=0.004).

The revisions per 100 component years for Microplasty UKR (0.87, CI 0.75-1.02) were significantly lower (p=0.02) than for Non Microplasty (1.11, CI 0.99-1.24). Microplasty inserted within a year of its introduction (n=2,424) and those inserted more than a year and after its introduction (n=5,529) had revision rates per 100 component years of 0.98 (CI 0.78-

1.22) and 0.79 (CI 0.63-0.99) respectively. When compared to the Non-Microplasty group, the decrease in revision rates of Microplasty inserted within a year of its introduction was not significant (0.98 v 1.11, p=0.34). Microplasty inserted more than a year after its introduction had significantly lower (0.79 v 1.11, p=0.008) revision rates than Non-Microplasty.

The indications for revision with the highest revision rates per 100 component years in Non-Microplasty UKRs were osteoarthritis progression (0.31), aseptic loosening (0.26) and pain (0.19) (Table 2). In Microplasty UKRs the highest revision rates per 100 component years were osteoarthritis progression (0.21), aseptic loosening (0.19) and pain (0.12) (Table 2). Microplasty UKRs had a significantly reduced revision risk per 100 component years compared to Non-Microplasty UKRs for indications; osteoarthritis progression ($p<0.05$, 0.21 vs 0.31) and "other reasons" (p=0.003, 0.08 vs 0.18). Microplasty assisted UKRs had a significantly increased risk of periprosthetic fracture (p=0.03, 0.09 vs 0.04). No other revision indications differed significantly between groups.

4. DISCUSSION

This study demonstrates that Microplasty instrumentation improves the 5 year implant survival of the Oxford UKR compared to the Non-Microplasty instrumentation and decreases the overall revision rate by 23%. Although previous studies have demonstrated that Microplasty usage results in improvement in various surrogate measures such as implant positioning [13, 14, 16], the need for tibial recuts [15] and tibial bone preservation [16], this is the first study which has investigated its effect on implant survival.

We found different effects on revision rate with time from Microplasty introduction. Microplasty UKRs inserted less than a year after its introduction to a hospital decreased the revision rate compared to Non Microplasty UKRs by 14%. However the difference was not statistically significant, partly because the numbers of cases was relatively small, so we do not know if there was a decrease in revision rate or not. In contrast Microplasty UKRs inserted more than a year after its introduction had a 31% reduction in revision rates compared to Non-Microplasty UKRs, which was highly statistically significant. The smaller decrease in revision rate during the first year after introduction is likely to be due, in part, to a delay in surgeons within a hospital changing to use Microplasty after the instruments had been supplied, as in many hospitals second and third Microplasty sets were introduced sometime after the first set. It may also, in part, be due to the learning curve. However as Microplasty, in the early period, did not increase the risk of revision relative to Non Microplasty the learning curve, if present, was not adverse as it was not associated with a temporary increase in implant failure rate. Furthermore the decrease in revision rate by one third (31%) seen later is likely to represent the true advantage of Microplasty.

It is difficult to interpret the analysis of the causes for revision primarily because the average follow-up of the Microplasty (2.3 years) and Non-Microplasty (3.3 years) UKR were different. A direct comparison of revision rates would be inappropriate because the numbers of revisions are related to the length of follow-up. The optimal method of comparison would be Kaplan Meier survival with Cox regression models, which we used for primary analysis of overall revision rate, as this is designed for the analysis of data from patients with different lengths of follow-up. However, as the number of revisions in each subgroup is low, this method is not appropriate. Another widely used approach is to use the revision rate per 100 component years, which is what we have used. However it is based on the assumption that the annual revision

rate is constant. This a reasonable assumption for the overall revision rate and the conclusions of the analysis over the overall revision rate using revisions per 100 component years and survival and cox regression were identical. However although is a reasonable assumption for many individual modes of failure it may not be for all. For example peri-prosthetic fractures tend to occur early so the group with a shorter follow up would be expected to have a higher revision rate. This may explain why Microplasty has a peri-prosthetic fracture rate that is just significantly higher than that of Non-Microplasty. Conversely arthritis progression tends to occur late so the group with a longer follow up would be expected to have a higher revision rate. This may explain why Non-Microplasty has an arthritis progression rate that is just significantly higher than that of Microplasty. The only other significant difference relates to "other reasons" for revision, so we don't know what these are. We therefore have to conclude that it is not clear why Microplasty has a lower revision rate but it is probably a result of the numerous improvements in the instruments.

With the Non-Microplasty instrumentation surgeons judged the position of the tibial component and the orientation of the femoral component by eye. Microplasty includes a stylus system for selecting tibial resection level and a guide to control femoral component orientation. It has other advantages including slotted saw guides and instruments to protect the medial collateral ligament and avoid impingement. In addition, as the instrumentation guides component positioning the surgeon can focus on what really matters, which is restoration of normal ligament balance, tension and function. If these are accurately restored normal knee kinematics and function will also be restored. Previous studies have shown that the use of Microplasty does result in improved component positioning, with better tibial bone preservation, thinner bearings and avoidance of tibial recuts [13, 14, 16]. It has also resulted in improved patient reported outcome measures [15]. Furthermore Microplasty has made the operation more simple, logical, reliable and repeatable [13, 14]. These improvements probably explain the overall decrease in revision rate: For example improved component position and the avoidance of impingement should decrease revisions for loosening, pain and dislocation; and protection of the medial collateral ligament should prevent overcorrection and lateral arthritis.

The main strength of the study is that it is large enough to study revision as it included over 15,000 knees. The study is also unbiased as it was based on NJR data, and data from the designer surgeons centre was not included in the analysis. The study is also long enough to

report the 5 year revision rate and showed that it was appreciably less with Microplasty than Non-Microplasty Instrumentation. But perhaps more importantly the 97% five-year survival of Microplasty UKR was not substantially worse than that achieved by TKR in National Registers [4, 6]. So the Microplasty instrumentation has gone a long way to addressing the main disadvantage of UKR, which is that it has a higher revision rate than TKR.

The main limitation of the study is that the precise date when individual surgeons changed from Non-Microplasty to Microplasty instrumentation is not known and the length of the learning curve is not known. As a result it was assumed that surgeons started using Microplasty as soon as it was introduced to their centre and that the transition period, which included the learning curve, lasted one year. Furthermore it is a possibility that some cases were done using other instrumentation, such as Patient Specific Instrumentation. However if other instrumentation was used the numbers would have been too small to influence the results. Another limitation is that the study is based on registry data and the only outcome assessed is revision. Furthermore the reasons for revision in the NJR are those recorded at the time of surgery even if this subsequently changed due to histopathology and microbiology data. Registries can under-report revisions [33] although there is no reason to believe this would differ between the groups, and it is not possible to confirm causality in registry based studies. Another limitation is that, despite propensity matching there is potential for residual confounding. The groups were not perfectly matched given there was imbalance in the operating surgeon grade and surgeon caseload. However there were no differences in findings when we adjusted for these parameters in the regression models. There was a substantial proportion of BMI data missing so we did not match on BMI. However, the BMI distribution between groups were the same both before and after propensity matching. The only way to achieve complete balance with respect to both known and unknown confounders is with a randomised trial. However to compare revision rates and causes for revision would require large numbers which would make a randomised study impractical.

5. CONCLUSIONS

In conclusion, this propensity matched registry based study observed that the five year survival of Microplasty assisted Oxford UKRs was 97%, which was significantly better than that of Non-Microplasty UKRs. Furthermore there was no adverse learning curve effect.

After the one-year transition period, the revision rate following Microplasty UKRs was about one third less than following Non Microplasty UKRs.

6. LIST OF TABLES

Table 1. Patient and surgical factors before and after propensity score matching. Abbreviations: ASA (American Society of Anesthesiologist score), BMI (Body mass index), OA (Osteoarthritis), SD (Standard deviation), SMD (Standardised mean difference), UKR (Unicompartmental knee replacement) VTE (Venous thromboembolism).

	Unmatched cohort				**Matched cohort**			
	All UKRs (n=23,234)	**Non Microplasty UKRs (n=12,210, 52.6%)**	**Microplasty assisted UKRs (n=11,024, 47.4%)**	**SMD**	**All UKRs (n=15,906, 100%)**	**Non Microplasty UKRs (n=7953, 50%)**	**Microplasty assisted UKRs (n=7953, 50%)**	**SMD**
Covariate								
Gender								
Female	10,453 (45.0%)	5,484 (44.9%)	4,969 (45.1%)	0.003	7,235 (45.5%)	3623 (45.6%)	3612 (45.4%)	0.003
Male	12,781 (55.0%)	6,726 (55.1%)	6,055 (54.9%)		8671 (54.5%)	4330 (54.4%)	4341 (54.6%)	
Age at surgery (yr)								
Mean (SD)	64.5 (SD 9.4)	64.3 (SD 9.4)	64.8 (SD 9.3)	0.06	64.5 (SD 9.5)	64.6 (SD 9.5)	64.5 (SD 9.4)	0.007
BMI (kg/m^2)*								
Mean (SD)	30.3 (SD 5 n=18,802)	30.1 (SD 4.9, n=9,245)	30.5 (SD 5.1, n=9,557)	0.08	30.4 (SD 5, n=12,965)	30.1 (SD 4.9, n=6134)	30.6 (SD 5.1, n=6831)	0.08
Primary diagnosis								
Primary OA	23,014 (99.1%)	12,092 (99%)	10,922 (99.1%)	0.004	15,752 (99.0%)	7,864 (98.9%)	6,888 (99.2%)	0.03
Other	220 (1%)	118 (1%)	102 (0.9%)		154 (1.0%)	89 (1.1%)	65 (0.8%)	
Bilateral UKRs	739 (3.2%)	435 (3.6%)	304 (2.8%)	0.05	484 (3.0%)	287 (3.6%)	197 (2.5%)	0.066
ASA grade								
1	4,380 (18.9%)	2395 (19.6%)	1985 (18.0%)	0.06	2,979 (18.7%)	1,575 (19.8%)	1,404 (17.7%)	0.05
2	16,857	8,833	8024		11,534	5,684	5840	

	(72.6%)	(72.3%)	(72.8%)		(72.5%)	(71.5%)	(73.6%)	
3 or above	1,997 (8.6%)	982 (8.0%)	1015 (9.2%)		1,393 (8.8%)	694 (8.7%)	699 (8.8%)	
VTE – chemical								
LMWH (+/- other)	13,912 (59.9%)	7,910 (64.8%)	6,002 (54.4%)	0.26	10,305 (64.8%)	5,081 (63.9%)	5,224 (65.7%)	0.05
Aspirin only	1,343 (5.8%)	676 (5.6%)	664 (6%)		1,022 (6.4%)	556 (7.0%)	466 (5.9%)	
Other	7,455 (32.1%)	3,259 (26.7%)	4,196 (38.1%)		4,286 (27.0%)	2,160 (27.2%)	2,126 (26.7%)	
None	524 (2.3%)	362 (3.0%)	162 (1.5%)		293 (1.8%)	156 (2.0%)	137 (1.7%)	
VTE – mechanical								
Any	22,973 (98.9%)	12,065 (98.8%)	10,908 (99.0%)	0.01	15,721 (98.8%)	7,883 (99.1%)	7,838 (98.6%)	0.05
None	261 (1.1%)	145 (1.2%)	116 (1.0%)		185 (1.2%)	70 (0.9%)	115 (1.5%)	
Surgeon grade								
Consultant	21,840 (94.0%)	11,768 (96.4%)	10,072 (91.4%)	0.21	14,988 (94.2%)	7,676 (96.5%)	7,312 (91.9%)	0.19
Other	1,394 (6.0%)	442 (3.6%)	952 (8.6%)		918 (5.8%)	277 (3.5%)	641 (8.1%)	
Surgeon caseload								
<10 cases/year	7,446 (32.1%)	4780 (39.1%)	2666 (24.2%)	0.33	5,073 (31.9%)	2919 (36.7%)	2154 (27.1%)	0.21
10 to <30 cases/year	10,112 (43.5%)	4776 (39.1%)	5336 (48.4%)		7,086 (44.6%)	3267 (41.1%)	3819 (48.0%)	
≥30 cases/year	5,676 (24.4%)	2654 (21.7%)	3022 (27.4%)		3,747 (23.6%)	1767 (22.2%)	1980 (24.9%)	

Surgical approach								
Medial parapatellar	21,121 (90.9%)	11,219 (91.9%)	9,902 (89.8%)	0.07	14,631 (92.0%)	7,385 (92.9%)	7,246 (91.1%)	0.06
Other	2,113 (9.1%)	991 (8.1%)	1,122 (10.2%)		1,275 (8.0%)	568 (7.1%)	707 (8.9%)	
Minimally invasive surgery								
0	12,325 (53.0%)	6,141 (50.3%)	6,184 (56.1%)	0.12	8,507 (53.5%)	4,063 (51.1%)	4,444 (55.9%)	0.09
1	10,909 (47.0%)	6,069 (49.7%)	4,840 (43.9%)		7,399 (46.5%)	3,890 (48.9%)	3,509 (44.1%)	
Fixation								
Cemented	12,939 (55.7%)	8,570 (70.2%)	4,369 (39.6%)	0.65	8,696 (54.7%)	4,350 (54.7%)	4,346 (54.7%)	0.001
Cementless	10,295 (44.3%)	3,640 (29.8%)	6,655 (60.4%)		7,210 (45.3%)	3,603 (45.3%)	3,607 (45.4%)	
Bone graft								
None	23,146 (99.6%)	12,157 (99.6%)	10,989 (99.6%)	0.02	15,842 (99.6%)	7,912 (99.5%)	7,930 (99.7%)	0.04
Bone graft used	88 (0.4%)	53 (0.4%)	35 (0.3%)		64 (0.4%)	41 (0.5%)	23 (0.3%)	

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438 **Table 2. Reasons for revision in matched cohort.** Comparisons between were Microplasty
439 and Non-Microplasty revisions per 100 component years were conducted using the Chi squared
440 test. Abbreviations: OA (Osteoarthritis), UKR (Unicompartmental Knee Replacement).
441 Significant p values are in bold and the indication for revision they correspond to are marked
442 with *.
443

Reasons for revision	Matched cohort						
	Non Microplasty absolute number of revisions	**Mean time to revision (Years)**	**Non Microplasty revisions per 100 component years**	**Microplasty absolute number of revisions**	**Mean time to revision (Years)**	**Microplasty revisions per 100 component years**	**Comparison of revisions per 100 component years (P value)**
Aseptic loosening	69 (0.87%)	2.3 (SD 1.3)	0.26	35 (0.44%)	1.5 (SD 0.9)	0.19	P=0.13
OA progression*	82 (1.03%)	2.8 (SD 1.4)	0.31	39 (0.49%)	1.9 (SD 1.0)	0.21	**P=0.048**
Pain	49 (0.62%)	2.3 (SD 1.1)	0.19	22 (0.28%)	1.5 (SD 0.7)	0.12	P=0.08
Other*	48 (0.60%)	2.0 (SD 1.4)	0.18	14 (0.18%)	1.2 (SD 0.8)	0.08	**P=0.003**
Dislocation subluxation revision	17 (0.21%)	1.5 (SD 1.5)	0.06	22 (0.28%)	1.1 (SD 0.8)	0.12	P=0.052
Instability	26 (0.33%)	2.3 (SD 1.1)	0.10	10 (0.13%)	1.4 (SD 0.8)	0.05	P=0.11
Component dissociation	18 (0.23%)	1.4 (SD 1.1)	0.07	12 (0.15%)	1.0 (SD 0.9)	0.07	P=0.91
Malalignment	23 (0.29%)	2.0 (SD 1.4)	0.09	11 (0.14%)	1.2 (SD 1.5)	0.06	P=0.30
Infection	12 (0.15%)	0.9 (SD 1.0)	0.05	13 (0.16%)	0.9 (SD 0.7)	0.07	P=0.27

Periprosthetic fracture*	10 (0.13%)	0.5 (SD 0.3)	0.04	16 (0.20%)	0.5 (SD 0.6)	0.09	**P=0.03**
Lysis	8 (0.1%)	2.7 (SD 0.9)	0.03	4 (0.05%)	2.2 (SD 1.3)	0.02	P=0.77
Wear	7 (0.09%)	2.9 (SD 1.4)	0.03	5 (0.06%)	1.7 (SD 1.7)	0.03	P=0.97
Stiffness	5 (0.06%)	2.4 (SD 1.3)	0.02	6 (0.08%)	1.8 (SD 1.8)	0.03	P=0.36
Implant fracture	0 (0%)		N/A	0 (0%)		N/A	N/A
Patellar wear	0 (0%)		N/A	0 (0%)		N/A	N/A
Tibial wear	0 (0%)		N/A	0 (0%)		N/A	N/A
Incorrect sizing	0 (0%)		N/A	0 (0%)		N/A	N/A
Patella mal tracking	0 (0%)		N/A	0 (0%)		N/A	N/A

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7. LIST OF FIGURES

8. DECLARATIONS

8.1 Acknowledgements

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8.2 Author contributions

HRM, GSM, AJ and DWM designed the study. HRM and GSM analysed the data with statistical support from AJ. HRM, GSM, AJ, and DWM helped with data interpretation. HRM wrote the initial manuscript draft which was then revised by all authors. All authors approved the final submitted manuscript.

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